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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/828,217

04/09/2001

Toshio Hirano

205721US0CON

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05/18/2005

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EXAMINER

OUSPENSKI, ILIA I

ART UNIT

PAPER NUMBER

1644

DATE MAILED: 05/18/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 09/828,217	<b>Applicant(s)</b> HIRANO ET AL.	
	<b>Examiner</b> ILIA OUSPENSKI	<b>Art Unit</b> 1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 25 February 2005.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 23-32 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 24-26 and 28 is/are allowed.
- 6) ☒ Claim(s) 30-32 is/are rejected.
- 7) ☒ Claim(s) 23,27 and 29 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### DETAILED ACTION

1. Applicant's amendment, filed 02/25/2005, is acknowledged.

Claims 11 – 22 have been cancelled.

Claims 1 – 10 have been cancelled previously.

Claims 23 – 32 have been added.

*Claims 23 – 32 are pending.*

2. This Office Action will be in response to applicant's arguments, filed 02/25/2005.

The rejections of record can be found in the previous Office Action, mailed 08/25/2004.

The text of those sections of Title 35 USC not included in this Action can be found in a prior Action.

It is noted that New Grounds of Rejection are set forth herein.

3. The disclosure is objected to for the following informalities:

A. Applicant is reminded of the proper language and format for an abstract of the disclosure. The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words.

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B. It is noted that the specification on pages 21 – 22, bridging paragraph discloses that the claimed hybridoma has been deposited at the National Institute of Bioscience and Human Technology in Japan, which is an international depository authority according to Budapest Treaty, on October 5, 1993, under accession number FERM BP-4433. However, the address of the depository has not been provided. The address is required to satisfy the deposit rules under 37 CFR 1.803. See MPEP 2405.

4. The claims are objected to for the following informalities:

A. In claims 23 and 27, a comma following “SEQ ID NO:1” is missing.

B. Claim 29 contains an apparently superfluous recitation “(RS38)” which is not a part of the accession number.

5. It is apparent that the cell lines U937 and K562 are required to practice the claimed invention. As a required element, they must be known and readily available to the public or obtainable by a repeatable method set forth in the specification.

It is determined by the Examiner that cell lines U937 and K562 are available without restriction from ATCC (10801 University Boulevard, Manassas, VA 20110-2209) under accession numbers CRL-1593.2 and CCL-243, respectively. As such, these cell lines satisfy the requirements of 37 CFR 1.801-1.809.

6. Claim rejection under **35 USC 112, first paragraph – New Matter rejection**: the rejection of record of claims 14 – 19, corresponding to newly added claims 23 – 29, has been obviated by Applicant’s amendment.

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7. Claim rejection under **35 USC 102(b)**: the rejection of record of claims 14 – 19, corresponding to newly added claims 23 – 29, has been obviated by Applicant's amendment.

*Therefore, claims 23 – 29 appear to be directed to allowable subject matter.*

8. It is noted that claims directed to methods, corresponding to the newly added claims 30 – 32, have been previously withdrawn from further consideration by the Examiner, under 37 C.F.R. § 1.142(b), as being drawn to nonelected inventions.

Claims 23 – 29 are directed to an allowable product. Pursuant to the procedures set forth in the Official Gazette notice dated March 26, 1996 (1184 O.G. 86), claims 30 – 32, directed to the process of making or using the patentable product, previously withdrawn from consideration as a result of a restriction requirement, are now subject to being rejoined. Claims 30 – 32 hereby rejoined and fully examined for patentability under 37 CFR 1.104.

Since all claims previously withdrawn from consideration under 37 CFR 1.142 have been rejoined, the restriction requirement made in the Office action mailed on 08/25/2004 is hereby withdrawn.

9. The following is a quotation of the second paragraph of 35 U.S.C. 112.

*The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.*

10. Claims 30 and 31 are rejected under **35 U.S.C. 112, second paragraph**, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 30 and 31 are indefinite because the methods do not clearly set forth a resolution step, which reads back on the preamble of the claimed method.

Applicant is reminded that any amendment must point to a basis in the specification so as not to add new matter. See MPEP 714.02 and 2163.06.

11. The following is a quotation of the first paragraph of 35 U.S.C. 112:

*The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.*

12. Claims 30 – 32 are rejected under **35 U.S.C. 112, first paragraph**, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. *This is a New Matter rejection.*

Applicant's amendment, filed 07/01/2004, asserts that no New Matter has been added and points to the specification at pages 1, 3 – 4, and 21 for support for the newly added method claims. However, the specification does not appear to provide an adequate written description of the following limitations: "contacting a synovial cell," "for a time and under conditions suitable for binding," "synovial cell from a subject having rheumatoid arthritis," "a subject suspected of having rheumatoid arthritis," "measuring binding," determining binding," and "the occurrence of, or the amount of, binding."

The instant claims now recite limitations which were not clearly disclosed in the specification and claims as filed, and now change the scope of the instant disclosure as filed. Such limitations recited in the present claims, which did not appear in the

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specification or original claims, as filed, introduce new concepts and violate the description requirement of the first paragraph of 35 U.S.C. 112.

*Applicant is required to cancel the New Matter in the response to this Office Action.* Alternatively, Applicant is invited to clearly point out the written support for the instant limitations.

13. Claim 30 is rejected under **35 U.S.C. 112, first paragraph**, because the specification, while being enabling for a method for identifying a synovial cell from a subject having rheumatoid arthritis, does not reasonably provide enablement for a method for identifying a synovial cell, as generically recited in the claim. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

The specification does not provide a sufficient enabling description of the claimed invention.

The specification discloses at pages 3 – 4, bridging paragraph, that the antibody of the invention recognizes a protein expressed on synovial cells derived from patients with rheumatoid arthritis, but not expressed on cells derived from healthy donors. Therefore, Applicant does not provide a sufficiently enabling disclosure regarding how to practice the claimed methods commensurate in scope with the breadth of the claim.

Reasonable correlation must exist between the scope of the claims and scope of enablement set forth. Without sufficient guidance, binding of the claimed antibody to synovial cells is unpredictable; thus the experimentation left to those skilled in the art, is unnecessarily, and improperly, extensive and undue.

14. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

15. Claims 30 – 32 are rejected under the judicially created doctrine of **obviousness-type double patenting** as being unpatentable over claims 1 – 3 of U.S. Patent No. 6,489,126. Although the conflicting claims are not identical, they are not patentably distinct from each other because they are directed to the same or nearly the same methods of identifying a cell expressing a polypeptide having pre-B cell growth-supporting ability. The instantly claimed methods of identifying a synovial cell by contacting the cell with an antibody to a polypeptide of SEQ ID NO:1 are anticipated by the Patent claims to a method of identifying cells expressing the same polypeptide of SEQ ID NO:1 using an antibody which recognizes the polypeptide.



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**16. Conclusion: claims 23 – 29 appear to be directed to allowable subject matter.**

17. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

18. Any inquiry concerning this communication or earlier communications from the examiner should be directed to ILIA OUSPENSKI whose telephone number is 571-272-2920. The examiner can normally be reached on Monday-Friday 9 - 5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

ILIA OUSPENSKI

Patent Examiner

Art Unit 1644

May 11, 2005

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PRIMARY EXAMINER  
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5/16/05